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Conditionally Required Chronic Mysid Study for Fluazaindolizine (DPX-Q8U80)

DATA REQUIREMENTS

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**GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT**

Title: Conditionally Required Chronic Mysid Study for Fluazaindoline (DPX-Q8U80)

Neither the U.S. EPA FIFRA (40 CFR Part 160) Good Laboratory Practice Standards nor the OECD Principles of Good Laboratory Practice (as revised (1997), ENV/MC/CHEM(98)17, OECD, Paris, 1998, are applicable to this document.

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## Conditionally Required Chronic Mysid Study for Fluazaindolizine (DPX-Q8U80)

*Author: T. Michelle Blickley, PhD*

### 1.0 SUMMARY

The purpose of this paper is to provide a rationale for waiving the conditionally required Chronic Mysid Toxicity Test (OPPTS guideline 850.1350, draft 1996) for the nematicide fluazaindolizine (DPX-Q8U80). Current acute and chronic data for aquatic organisms indicates low/acceptable risk. Furthermore, sufficient data is available to calculate a chronic No Effect Concentration (NOEC) for mysid shrimp.

### 2.0 EVALUATION

According to 40 CFR Subpart G – Ecological Effects, 158.630 Terrestrial and aquatic nontarget organisms data table, the OPPTS 850.1350 Chronic Mysid Toxicity Test is required if the product meets **any** of the following conditions:

- i. Intended for direct application to the estuarine or marine environment.
- ii. Expected to enter this environment in significant concentrations because of its expected use or mobility patterns.
- iii. If the acute LC<sub>50</sub> or EC<sub>50</sub> < 1 mg/L.
- iv. If the estimated environmental concentration (EEC) in water is  $\geq 0.01$  of the acute LC<sub>50</sub> or EC<sub>50</sub> or if **any** of the following exist:
  - A. Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected.
  - B. Physicochemical properties indicate bioaccumulation of the pesticide.
  - C. The pesticide is persistent in water (e.g., half-life in water > 4 days).

While the proposed use pattern does not include direct application to estuarine or marine environments, fluazaindolizine is expected to enter estuarine or marine environments adjacent to the field. EECs are  $\leq 276$   $\mu\text{g/L}$  when modelled with PWC v1.52 at a use rate of 2 lb/acre, 2 applications with a 21 day interval in spring or fall.

#### *Acute hazard and risk to aquatic invertebrates*

Acute daphnid (OECD 202, 2004; OPPTS 850.1010, 1996) and mysid (OPPTS 850.1035, 1996) hazard endpoints are shown in Table 1. The EC<sub>50</sub>/LC<sub>50</sub> values are >120 and > 30 mg a.i./L, respectively, which is well above 1 mg/L threshold. Calculation of the risk quotient values (RQs = EEC/EC<sub>50</sub>) using the maximum EEC listed above indicate low risk as the RQs are an order of magnitude below the acute Level of Concern (LOC) of 0.05 for endangered species.

*Chronic hazard and risk to aquatic invertebrates and fish*

A chronic daphnid study (OECD 211, 2012; US EPA OPPTS 850.1300, 1996) was conducted with fluazaindolizine. The most sensitive endpoint of the study was reproduction (NOEC = 1.2 mg a.i./L) therefore the RQ value is an order of magnitude lower than the chronic LOC of 1.

Early life stage (ELS) studies in fathead and sheepshead minnow (OECD 210, 2013; US EPA 850.1400, 1996) are available (Table 1). For fathead minnow there were no treatment-related effects on hatching success, time to hatch, time for larvae to swim-up, post hatch survival or on post-hatch growth (total length, wet and dry weights) up to and including concentrations of 12 mg a.i./L, the highest concentration tested. However, in sheepshead minnow there were effects on hatching success, mortality, and growth. Using the NOEC of 1.5 mg a.i./L, the RQ value is an order of magnitude lower than the chronic LOC of 1.

*Bioaccumulation potential*

Given the low Kow value of fluazaindolizine (range: 0.19 to 174), it is unlikely to bioaccumulate in the tissues of fish and other nontarget aquatic organisms (Table 2).

*Calculation of a mysid chronic NOEC*

Based on the above criteria listed in the 40 CFR Subpart G, a chronic mysid study would be triggered based on the reproductive effects measured in the chronic daphnid and sheepshead minnow ELS studies. However, using the available acute daphnid, acute mysid, and chronic daphnid endpoints, a chronic mysid NOEC of 0.3 mg a.i./L was derived using the Acute:Chronic (A:C) ratio from the daphnid endpoints (120/1.2 = 100). The RQ value for the calculated mysid chronic endpoint is below the chronic LOC of 1 indicating low risk. Additionally, the acute daphnid and mysid values used in the A:C calculation are greater than values (>) versus a definitive endpoint, which conveys additional protection to the taxa.

### 3.0 CONCLUSIONS

Current acute and chronic data for fish and aquatic invertebrates indicates low risk from exposure to fluazaindolizine. Furthermore, sufficient data is available to calculate a chronic NOEC of 0.3 mg a.i./L for mysid shrimp thus negating the need to conduct the study.

## 4.0 REFERENCES

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- Pushpalatha, K.G. 2013. DPX-Q8U80: Laboratory Study of n-Octanol/Water Partition Coefficient. Advinus Therapeutics Limited, Bangalore, India. DuPont-35462



**Table 1**  
**Relevant aquatic organisms hazard endpoints for fluazaindolizine (DPX-Q8U80)**

Species	Exposure system	Results	Reference
<b>Invertebrates</b>			
<i>Daphnia magna</i>	48 hr, static	EC <sub>50</sub> > 120 mg a.i./L <sup>†</sup>	DuPont-36623
<i>Americamysis bahia</i> , Mysid shrimp	96 hr, static	LC <sub>50</sub> > 30 mg a.i./L <sup>†</sup>	DuPont-38322
<i>Daphnia magna</i>	21 d, static-renewal*	NOEC = 1.2 mg a.i./L	DuPont-38321
<b>Fish</b>			
<i>Oncorhynchus mykiss</i> , Rainbow trout	87 d (ELS), ft	NOEC = 12 mg a.i./L <sup>†</sup>	DuPont-40682
<i>Cyprinodon variegatus</i> , Sheepshead minnow	34 d (ELS), ft	NOEC = 1.5 mg a.i./L	DuPont-41199

\* test solutions renewed every 2-3 days; † highest concentration tested

**Table 2**  
**Environmental fate parameters of fluazaindolizine (DPX-Q8U80)**

<b>Molecule</b>	<b>Kow</b>	<b>Log Kow</b>	<b>Reference</b>
Fluazaindolizine	At pH 4, Kow = 174 At pH 7, Kow = 0.69 At pH 9, Kow = 0.19	At pH 4, log Kow = 2.24 At pH 7, log Kow = -0.16 At pH 9, log Kow = -0.71	DuPont-35462